K120229

SECTION 5. 510(k) Summary

FEB 2 4 2012

(As Required By 21 CFR 807.92(a))

A. Submitter Information

Submitter's name: Codman & Shurtleff, Inc.
Address: 325 Paramount Drive
Raynham, MA 02767
Telephone: 508-828-3312
Fax: 508-977-6428
Contact Person: Catherine Kilshaw
Date of Submission: December 16, 2011

B. Trade/Device Name: ENVOY® Distal Access Guiding Catheter

Common Name: ENVOY® Distal Access Guiding Catheter
Classification Name: Percutaneous Catheter
Regulation Number: Class II per 21 CFR 870.1250

C. Predicate Devices:

Device	Company	510(k) Number/ Concurrence Date	Product Code	Predicate For:
Primary Predicate: ENVOY® Guiding Catheter	Codman & Shurtleff, Inc.	K982770	DQY	Intended Use Design Materials Manufacturing Sterilization
Neuropath® Guiding Catheter	Codman & Shurtleff, Inc. (previously Micrus)	K052004	DQY	Materials
REVIVE™ Intermediate Catheter	Codman & Shurtleff, Inc.	K112828	DQY	Materials

D. Device Description:

The ENVOY® Distal Access (DA) Guiding Catheter is a variable stiffness, braided catheter with a large non-tapered lumen that facilitates the intravascular passage of interventional devices. The distal segment is flexible for navigation into distal vasculature. The catheter has an outer hydrophilic coating that reduces friction during manipulation in the vessel. The lubricious PTFE lined inner lumen is designed to facilitate movement of the guide wires and other devices. A luer fitting located on the end of the catheter hub can be used to attach accessories. The distal section of the catheter is radiopaque to aid visualization under fluoroscopy, and the distal tip is clearly distinguished by a radiopaque marker. The catheter is available with preshaped tips to

facilitate positioning. A peel away introducer is included to facilitate insertion into the sheath.

E. Intended Use:

The ENVOY® Distal Access Guiding Catheter is intended for use in the peripheral, coronary, and neuro vasculature for the intravascular introduction of interventional/diagnostic devices.

F. Summary of technological characteristics of the proposed to the predicate device:

The ENVOY DA Guiding Catheter is substantially equivalent to the Codman ENVOY Guiding Catheter. No new technological characteristics are being introduced with the proposed device.

The ENVOY DA has the same intended use as the Codman ENVOY Guiding Catheter, and it is similar with regard to design, materials, manufacturing, and sterilization process.

The ENVOY DA also has the same intended use as the Neuropath Guiding Catheter and the REVIVE Intermediate Catheter. ENVOY DA is similar to Neuropath and REVIVE IC with regard to materials.

G. Testing Summary:

Preclinical testing data to demonstrate that the device performs according to its description and intended use were used to establish the performance characteristics of the modifications to this device. Clinical testing was not required to establish substantial equivalence.

Results of verification and validation conducted on the ENVOY DA Guiding Catheter demonstrate that it performs as designed, is suitable for its intended use, is substantially equivalent to the predicate device and therefore, does not raise any new issues of safety and effectiveness.

The following tests were conducted on the ENVOY DA guiding catheter:

- Aseptic removal of the guiding catheter from the packaging
- Visual Inspection/ Hub Transition
- Catheter Shape (post sterilization)
- Catheter Dimensional Verification
- Coating Length Verification
- Torque Testing
- Proximal Lateral Stiffness Test
- Back up Support
- Distal Tip lateral and Linear Stiffness Test
- Catheter Shaft Tensile Strength
- Catheter Tip Tensile Strength
- Hub Attachment Tensile Strength
- Coating Integrity
- Compatibility with Guidewires
- Trackability
- King Resistance (Distal & Proximal Shaft)
- Ovalization Testing
- System Liquid Leakage
- System Air Leakage
- Stability with Access Devices
- Hub Luer Taper
- Compatibility with REVIVE Intermediate Catheter
- Delamination of PTFE liner

The following tests were conducted on the Peel Away Introducer:

- Visual Inspection
- Dimensional Verification
- Shaft Peel Strength
- Hub detachment from the shaft

The ENVOY DA met all the biocompatibility requirements as specified by the ISO 10993 Part I, and the General Program Memorandum # G95-1 on Biological Evaluation of Medical Devices. The following tests were conducted:

- Cytotoxicity
- Sensitization

- Irritation
- Systemic Toxicity
- Hemocompatibility
- Thrombogenicity
- Genotoxicity
- Physicochemical

Based upon the design, materials, function, intended use, comparison with currently marketed devices, and the non-clinical testing performed by Codman & Shurtleff, Inc., it is concluded that the ENVOY DA Guiding Catheter is substantially equivalent to the ENVOY Guiding Catheter, Neuropath Guiding Catheter and REVIVE Intermediate Catheter and therefore, does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Codman & Shurtleff, Inc.
c/o Ms. Catherine Kilshaw
Regulatory Affairs Specialist II
325 Paramount Drive
Raynham, MA 02767-6428

FEB 2 4 2012

Re: K120229
Trade/Device Name: Envoy® Distal Access Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: January 24, 2012
Received: January 25, 2012

Dear Ms. Kilshaw:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120229

Device Name: Envoy Distal Access Guiding Catheter

Indications For Use:

The Envoy Distal Access Guiding Catheter is intended for use in the peripheral, coronary, and neurovasculature for the intravascular introduction of interventional/diagnostic devices.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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